: 4165-15-P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Health Resources and Services Administration** 

Updates to Uniform Standard for Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Request for public comment on updates to uniform standard for waiver of the Ryan White HIV/AIDS Program core medical services expenditure requirement.

SUMMARY: The Ryan White HIV/AIDS Program (RWHAP) statute of the Public Health Services Act requires that RWHAP Part A, B, and C recipients expend 75 percent of Parts A, B, and C grant funds on core medical services for individuals with HIV/AIDS identified and eligible under the statute, after reserving statutory permissible amounts for administrative and clinical quality management costs. The statute also grants the Secretary authority to waive this requirement if certain requirements are met. HRSA is proposing to simplify the process for RWHAP Part A, B, and C recipients to request a waiver of the core medical services expenditure amount requirement by replacing HRSA Policy Number 13-07, "Uniform Standard for Waiver of Core Medical Services Requirement for Grantees Under Parts, A, B, and C" (accessible at the following link) https://hab.hrsa.gov/sites/default/files/hab/Global/13-07waiver.pdf. This notice seeks to make public the proposed policy and provide an opportunity for public comment before its implementation. In a separate notice entitled, Updates to Uniform Standard for Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement, OMB No. 0906 – XXXX – NEW, HRSA is inviting comments on the data collection changes associated with this proposed policy change.

**DATES:** Submit comments no later than [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The policy will become effective on October 1, 2021.

ADDRESSES: Electronic comments on this policy should be sent to

RyanWhiteComments@hrsa.gov by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER ].

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Commander Emeka Egwim, U.S. Public Health Service, Senior Policy Analyst, Division of Policy & Data, HRSA, HIV/AIDS Bureau, 5600 Fishers Lane, Rockville, MD 20857, Phone: (301) 945-9637 or by emailing RyanWhiteComments@hrsa.gov.

**SUPPLEMENTARY INFORMATION:** The RWHAP statute grants the Secretary authority to waive this requirement for RWHAP Parts A, B, or C recipients if a number of requirements are met and a waiver request is submitted to HRSA for approval. RWHAP Part A, B, and C core medical services waiver requests – if approved – are effective for a 1-year budget period, and apply to funds awarded under the Minority AIDS Initiative.

Currently, for a core medical services waiver request to be approved, (1) core medical services must be available and accessible to all individuals identified and eligible for the RWHAP in the recipient's service area within 30 days, without regard to payer source; (2) there cannot be any AIDS Drug Assistance Program (ADAP) waiting lists in the recipient's service area; and (3) a public process to obtain input on the waiver request from impacted communities, including clients and RWHAP-funded core medical services providers, on the availability of core medical services and the decision to request the waiver must have occurred. The public process may be a part of the same one used to seek input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, statewide coordinated statement of need, public planning, and/or needs assessment processes.

The proposed changes would reduce the administrative burden for recipients by lessening the documentation they must submit to HRSA when requesting a waiver. Under the proposed policy, recipients would be required to submit a one-page "HRSA RWHAP Core Medical Services Waiver Request Attestation Form" to HRSA in lieu of the multiple documents currently required to submit a waiver request. Waiver request submission deadlines would also be revised. When finalized, the policy would replace HIV/AIDS Bureau (HAB) Policy Number 13-07 effective October 1, 2021, and would be named "Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement."

Summary of Proposed Changes: Currently, all waiver requests must be signed by the Chief Elected Official or the project director, and include several documents, regardless of when they are submitted relative to the grant application. The documents required under the current waiver request process outlined in HAB Policy Number 13-07 are: (1) a letter signed by the Director of the RWHAP Part B state/territory recipient indicating that there is no current or anticipated ADAP services waiting list in the state/territory; (2) evidence that all core medical services listed in the statute are available and accessible within 30 days for all identified and eligible individuals with HIV in the service area; (3) evidence of a public process; and (4) a narrative of up to 10 pages.

HRSA has determined that some of this required information is duplicative of information recipients already submit as part of recipients' grant applications or other reporting requirements. The current documentation for preparing and submitting waiver requests requires a substantial amount of time for recipients. Likewise, HRSA requires a substantial amount of time to review and process them. Therefore, HRSA is proposing that recipients submit the proposed "HRSA RWHAP Core Medical Services Waiver Request Attestation Form" in lieu of the supporting documentation required per HAB Policy Number 13-07. HRSA may request additional information or supporting documentation upon request.

### **Availability of Core Medical Services**

Currently, consistent with HAB Policy Number 13-07, recipients requesting core medical services waivers must provide evidence that all core medical services listed in the RWHAP statute are available for all identified and eligible individuals with HIV/AIDS in the service area without regard to the source of funding. However, as part of their grant application, RWHAP Part A, B, and C recipients provide sufficient information to satisfy this requirement. RWHAP Part A recipients describe the comprehensive system of care in the entire eligible metropolitan area or transitional grant area. This description includes the available core medical and support services funded by RWHAP Part A and other funding sources (including Minority AIDS Initiative funds), where those services are located, and how clients may access those services. Similarly, RWHAP Part B recipients provide a general description of the HIV service delivery system in the state/territory, including what services are available, where those services are located, and how clients may access those services. RWHAP Part C recipients also provide a description of services available to people with HIV in the entire designated service area; a map showing locations of all current and proposed local providers of HIV outpatient primary health care services, including the recipient's organization; and a list of all public and private organizations that provide HIV outpatient primary health care services to people with HIV in the entire designated service area. Therefore, it is duplicative to require additional documentation of this information separately as part of the core medical services waiver application.

# **ADAP Waiting Lists**

Consistent with the current requirements outlined in HAB Policy Number 13-07, recipients requesting core medical services waivers are required to submit a letter from the director of the RWHAP Part B state/territory recipient indicating there are no current or anticipated ADAP services waiting lists in the service area. All RWHAP Part B recipients already indicate in their grant applications whether there are ADAP waiting lists in their state or territory, and whether the recipient anticipates implementing one. Under the proposed changes, RWHAP Part A, B, and C recipients must still attest that there are no ADAP waiting lists in the

RWHAP Part B program on the RWHAP Core Medical Services Waiver Request Attestation Form to HRSA.

### **Evidence of a Public Process**

Currently, recipients submitting waiver requests also submit letters from the Planning Council Chair(s) and the state HIV/AIDS director describing the public process that occurred in the jurisdiction related to the availability of core medical services and the decision to request a waiver. RWHAP program recipients describe how they engaged affected communities regarding the availability of core medical services as part of their grant applications, and include evidence describing the community input process and how it informs the priority setting and resource allocation process for the jurisdiction. Specifically, the community input process described in RWHAP Part A grant applications addresses how data were used in the priority setting and allocation processes to increase access to core medical services. RWHAP Part B recipients' grant applications include needs assessments that in part, describes the Public Advisory Planning Process models to ensure inclusion of people with HIV, other RWHAP recipients, other HIV related programs, other general and local stakeholders, and community leaders. Similarly, RWHAP Part C recipients' grant applications include documentation on the process used to obtain community input on the design and implementation of activities related to the grant. HRSA notes that these public processes are not done in the context of RWHAP Part A, B, or C recipients requesting waivers of the RWHAP core medical services expenditure requirements. Therefore, consistent with the requirements outlined in the statute, RWHAP Parts A, B, and C recipients should ensure the completion of a public process to obtain input on their desire to request a core medical services waiver prior to submitting the HRSA RWHAP Core Medical Services Waiver Request Attestation Form.

In addition to the three requirements outlined above and in HAB Policy Number 13-07, HRSA currently requires recipients to submit a narrative of up to 10 pages describing how their proposed percentage allocation will allow for services to be provided if the waiver is granted.

These narratives also include any underlying local or state issues that influenced the decision to request a waiver, a proposed resource allocation table, as well as a description of the general healthcare landscape in the service area and how it may have changed over time. Given that recipients provide this information as part of the narrative in their grant applications or other submitted documentation, when a recipient submits a core medical services waiver application under the proposed policy, HRSA would be able to refer to that information or could request additional information from the recipient if needed.

For the reasons outlined above, HRSA has determined that these duplicative requirements outlined in HAB Policy Number 13-07 are administratively burdensome and can be reduced with a more streamlined process. The proposed policy would replace waiver requests with a one-page "HRSA RWHAP Core Medical Services Waiver Request Attestation Form (see below)." The Chief Elected Official, Chief Executive Officer, or a designee of either, would complete and submit the HRSA RWHAP Core Medical Services Waiver Request Attestation Form to HRSA certifying that the recipient has met the requirements outlined in the RWHAP statute and the new policy notice. This attestation form would be included as the last page of HAB Policy Notice 21-01, and would consist of the following:

- Instructions stating the form is to be completed by the Chief Elected Official, Chief
   Executive Officer, or a designee of either, and the person completing it should initial
   the included checkboxes to attest to meeting each requirement after reading and
   understanding its explanation.
- 2. A field in which the recipient can fill in its name.
- 3. Checkboxes with which the recipient can indicate the following:
  - a. If they are a RWHAP Part A, B, or C recipient
  - b. Whether the request is an initial request or renewal request
  - c. The year the waiver is being requested
- 4. Checkboxes with which the recipient attests to meeting the following requirements:

- a. Not having an ADAP waiting list
- Availability of and accessibility to core medical services to all eligible individuals within the service area within 30 days
- c. Evidence of having conducted a public process
- 5. Fields for the following details of the official completing the form:
  - a. Signature
  - b. Printed name
  - c. Title
- 6. The date the form was signed

# HRSA Ryan White HIV/AIDS Program (RWHAP) Core Medical Services Waiver Request Attestation Form

This form is to be completed by the Chief Elected Official, Chief Executive Officer, or a designee of either.

Please initial to attest to meeting each requirement after reading and understanding the explanation.

Name of recipient	
RWHAP Part A reci	pient RWHAP Part B recipient RWHAP Part C recipient
Initial request	Renewal request
/ear of request	
REQUIREMENT No ADAP waiting lists	EXPLANATION  By initialing here and signing this document, you attest there are no AIDS Drug Assistance Program (ADAP) waiting lists in the service area.
Availability of, and accessibility to core medical services to all eligible individuals	By initialing here and signing this document, you attest to the availability of and access to core medical services for all HRSA RWHAP eligible individuals in the service area within 30 days. Such access is without regard to funding source, and without the need to spend on these services, at least 75 percent of funds remaining from your RWHAP award after reserving statutory permissible amounts for administrative and clinical quality management. You also agree to provide HRSA HAB supportive evidence of meeting this requirement upon request.
Evidence of a public process	By initialing here and signing this document, you attest to having had a public process during which input related to the availability of core medical services and the decision to request this waiver was sought from impacted communities, including clients and RWHAP funded core medical services providers. You also agree to provide supportive evidence of such process to HRSA HAB upon request.
SIGNATURE OF CHIEF	ELECTED OFFICIAL OR CHIEF EXECUTIVE OFFICER (OR DESIGNEE)  PRINT NAME  TITLE
	DATE

Although the proposed policy's purpose is to reduce administrative burden for recipients, if finalized, it would not change the underlying requirements necessary to obtain a waiver, i.e., ensuring that: (1) all core medical services are available and accessible within 30 days in the jurisdiction or service area, (2) the state ADAP has no waiting lists, and (3) the recipient has

used a public process to determine the need for a waiver. The HRSA RWHAP Core Medical Services Waiver Request Attestation Form provides recipients applying for waivers the ability to attest to having satisfied these requirements. Notwithstanding, recipients may still be required to provide further information to HRSA upon request.

### **Submission Deadlines**

In addition to reducing the volume of documentation, HRSA is proposing to change the deadlines for submitting waiver requests.

Currently, consistent with the process outlined in HAB Policy Number 13-07, RWHAP Parts A, B, and C recipients may choose to submit a waiver request at any time prior to submission of the annual grant application, with the annual grant application, or up to 4 months after the start of the grant year for which the waiver is being requested.

To facilitate a more efficient review of waiver requests, the proposed changes would require waiver requests to be submitted by specific programmatic deadlines. A RWHAP Part A recipient would submit their waiver request as an attachment with the annual grant application or non-competing continuation (NCC) progress report. Because RWHAP Part B recipients submit their final budget 90 days after receiving their Notice of Award, the need for a waiver may not be identified until the final budget is approved. Therefore, a RWHAP Part B recipient would submit their waiver request either in advance of the grant application, with the grant application, with the mandatory NCC progress report, or up to 4 months into the grant award budget period for which the waiver is being requested. A RWHAP Part C recipient would submit their request for a waiver as an attachment with the grant application or the mandatory NCC progress report. These proposed changes are intended to better align waiver requests with programmatic processes, thereby allowing HRSA to better manage the review and processing of waiver requests.

The proposed policy maintains that applicants submit their waiver requests with their grant applications through <a href="www.grants.gov">www.grants.gov</a>. Recipients submit their waiver requests with the

mandatory NCC progress report through the Electronic Handbooks (EHB). For waiver requests that are not submitted with grant applications or the mandatory NCC progress report, the proposed policy would require a recipient to notify its HRSA project officer (PO) of its intention to request a waiver in order to initiate a request for information in the EHB.

In the current process, HRSA reviews requests and notifies recipients of waiver approval or denial no later than the date of issuance of the Notices of Award. In the proposed process, HRSA would notify recipients of waiver approval or denial within 4 weeks of receipt of the request, thereby saving weeks when compared to the current process. As with the current process, approved core medical services waivers will be effective for the 1-year budget period for which they are approved; recipients must submit a new request for each budget period. Also as with the current process, a recipient would not be required to implement an approved waiver should it no longer be needed.

Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure
Requirement

HAB Policy Notice 21-01

Replaces HAB Policy Number 13-07

**Scope of Coverage** 

HRSA HIV/AIDS Bureau RWHAP Parts A, B, and C.

**Purpose of Policy Notice** 

This HRSA policy notice replaces HAB Policy Number 13-07 Uniform Standard for Waiver of Core Medical Services Requirement for Grantees Under Parts, A, B, and C. It provides modified processes and requirements for HRSA RWHAP Parts A, B, and C recipients to request waivers of the statutory requirement regarding expenditure amounts for core medical services.

Requirements

A RWHAP Part A, B, or C recipient must meet a number of requirements, and submit a waiver request to HRSA to receive a waiver of the core medical services expenditure requirement.

- Core medical services must be available and accessible to all individuals identified and eligible for the RWHAP in the recipient's service area within 30 days. This access must be:
  - a. without regard to payer source, and
  - b. without the need to spend at least 75 percent of funds remaining from the recipient's RWHAP award after statutory permissible amounts for administrative and clinical quality management costs are reserved.
- 2. The recipient must ensure there are no ADAP waiting lists in its service area.
- 3. A public process to obtain input on the waiver request must have occurred.
  - a. This process must seek input from impacted communities including clients and RWHAP-funded core medical services providers on the availability of core medical services, and the decision to request the waiver.
  - b. The public process may be a part of the same one used to seek input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, statewide coordinated statement of need, public planning, and/or needs assessment processes.

# Requesting a Waiver

To request a waiver, the Chief Elected Official, Chief Executive Officer, or a designee of either must complete and submit the HRSA RWHAP Core Medical Services Waiver Request Attestation Form (appended below) to HRSA. The form should be submitted according to the applicable deadlines and methods for submission outlined below. By completing and submitting this form, the Chief Elected Official, Chief Executive Officer, or a designee of either attests to meeting the requirements outlined above and agrees to provide supportive evidence to HRSA upon request. No other documentation is required to be submitted with the HRSA RWHAP Core

Medical Services Waiver Request Attestation Form, although recipients may be required to submit additional documentation to HRSA upon request.

### **Deadlines for Submitting Waiver Requests**

RWHAP Part A waiver requests

A HRSA RWHAP Part A recipient should submit their request for a waiver as an attachment with the grant application or the mandatory NCC progress report, if applicable. In each case, waiver requests do not count towards the submission page limit. Do not submit requests for waivers prior to the grant application or mandatory NCC progress report, nor after the start of the grant award budget period for which the waiver is being requested.

RWHAP Part B Waiver Requests

A HRSA RWHAP Part B recipient may submit their request for a waiver either in advance of the grant application, as an attachment to the grant application, with the mandatory NCC progress report, or up to 4 months into the grant award budget period for which the waiver is being requested.

RWHAP Part C Waiver Requests

A HRSA RWHAP Part C recipient should submit their request for a waiver as an attachment to the grant application or the mandatory NCC progress report. Do not submit requests for waivers prior to the grant application or mandatory NCC progress report, nor after the start of the grant award budget period for which the waiver is being requested.

# **Methods for Submitting Waiver Requests**

Applicants must submit their waiver requests with their grant applications through <a href="www.grants.gov">www.grants.gov</a>. Recipients must submit their waiver requests with the mandatory NCC progress report through the Electronic Handbooks (EHB). Recipients who do not submit their waiver requests with their grant applications, or with their mandatory NCC progress reports must notify its HRSA PO of its intention to request a waiver. The PO will initiate a Request for

Information in the EHB. The recipient must respond to the EHB task consistent with the

deadlines for submitting waiver requests outlined above.

**Waiver Review and Notification Process** 

HRSA will review requests and notify recipients of waiver approval or denial within 4

weeks of receipt of the request.

Approved core medical services waivers will be effective for the 1-year budget period for

which it is approved; recipients must submit a new request for each budget period. A recipient

approved for a core medical services waiver is not required to implement the waiver if it is no

longer needed.

Diana Espinosa,

Acting Administrator.

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